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10/507,548

07/18/2005

Siegfried Ansorge

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06/09/2009

HODGSON RUSS LLP

THE GUARANTY BUILDING

140 PEARL STREET

SUITE 100

BUFFALO, NY 14202-4040

EXAMINER

MOHAMED, ABDEL A

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

06/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/507,548

Applicant(s)

ANSORGE ET AL.

Examiner

Abdel A. Mohamed

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-9, 11 and 14 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-8 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/18/09 has been entered.

ACKNOWLEDGMENT OF AMENDMENT, REMARKS AND STATUS OF THE CLAIMS

2. The amendment and remarks filed 05/18/09 are acknowledged, entered and considered. In view of Applicant's request claims 6 and 11 have been amended and claims 1-5, 10, 12, 13 and 15-42 have been canceled. Claims 6-9, 11 and 14 are now pending in the application of which claims 9 and 14 are withdrawn. The objection of the specification in regard to arrangement of the specification, the rejections under 35 U.S.C. 112, first paragraph in regard to treatment all kinds of dermatological conditions and/or diseases in a patient and 35 U.S.C. 102(e) over the prior art of record are withdrawn in view of Applicant's amendment and remarks filed 05/18/09. However, Applicant's remarks with respect to the rejection under 35 U.S.C. 102(e) over the prior art of record have been considered but deemed to be moot in view of the new ground of rejection under 35 U.S.C. 102(a) as set forth *infra*.

NEW GROUND OF REJECTION

CLAIMS REJECTION-35 U.S.C. § 102(a)

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 6-8 and 11 are rejected under 35 U.S.C. 102(a) as being anticipated by Ansonge et al WO 02053170 published 11 Jul 2002) (Ansonge et al, U.S. Patent No. 7,229,969 is the 371 filing thereof so for convenience, the US publication will be used as the English language translation of the foreign language document).

It is noted that the WO 02053170, filed 12/21/01 was not published in English, and the reference does not have a 102(e) date. However, the 102(e) has been withdrawn and modified to 102(a) rejection in view of its publication date, and as such, the '170 patent is citable for the instant rejection (i.e., for 102(a)).

Therefore, the Examiner reiterate the previous rejection, although, Applicant has limited the claims as currently amended to a method for therapy of acne and/or acneiform follicular reaction. Nevertheless, previously Applicant has argued that Figure 13 of '969 patent is not identical to Figure 2 of the instant application and is in fact different. Figure 13 of '969 patent relates to mRNA expression in HaCat keratinocytes. Figure 2 of the instant application relates to mRNA expression of in SZ95 sebocytes. It is well known in the art that keratinocytes and sebocytes are very different cell types, and have different genesis, different structures, and different functions in the human

body. Thus, the same is applicable for the respective conditions caused by proliferating sebocytes versus keratinocytes. Therefore, patients in need of therapy for one condition are distinct from those in need of therapy for the other. The '969 patent accordingly does not anticipate the present application is unpersuasive.

Contrary to Applicant's arguments, the claims are still drawn to administering a composition comprising inhibitors of dipeptidylpeptidase IV (DP IV) wherein the DP inhibitor is (Lys-[ZNO₂]-thiazolidide and/or inhibitors of alanyl aminopeptidase (aminopeptidase N or APN) and of enzymes having similar substrate specificity (APN-analogous enzyme activity) for the inhibition of the proliferation (DNA synthesis) of human sebaceous cells.

Further, the reference of Ansorge et al ('969 patent) discloses combination of inhibitors of DP IV such as (Lys-[ZNO₂]-thiazolidide having the same substrate specificity (DP IV-analogous enzymatic activity) and inhibitors of alanyl aminopeptidase (aminopeptidase N, APN) and of enzymes having the same substrate specificity (APN-analogous enzymatic activity) for inhibition and for treatment of diseases such as dermatological diseases with follicular and epidermal hyperkeratoses and enhanced proliferation of keratinocytes.

With respect to Applicant's arguments that it is well known in the art that keratinocytes and sebocytes are very different cell types, and have different genesis, different structures, and different functions in the human body. Thus, the same is applicable for the respective conditions caused by proliferating sebocytes versus keratinocytes. The Examiner acknowledges that keratinocytes and sebocytes are

different cell types; however, the instantly claimed invention is enabled for administering the claimed compound to a specific population or patients having disease pattern and/or conditions associated with acne and/or acne follicular reaction. Although, Figure 2 of the instant invention is not identical with Figure 13 of '969 patent as argued by Applicant, nevertheless, there is sufficient evidence of similarity which is deemed to be present between the instantly claimed invention of claims 6-8 and 11 and the '969 patent's teachings as disclosed in the abstract, col. 7, lines 43-45, Examples 1-13 and figure 13. For further support, see the reference of (Harper et al, Acne Vulgaris, The Medscape Journal for emedicine web site <http://www.emedicine.com/derm/TOP1C2.HTM>, updated July, 15, 2008, pages 1-11, provided on Form PTO 892). The reference clearly discloses that Acne vulgaris is a disease characterized by both proliferation of keratinocytes and follicular hyperproliferation, and as such, using the same compound (i.e., compounds claimed and disclosed by '969 patent) would inherently must treat sebocytes because it is the same population being treated (i.e., patients having disease pattern and/or condition associated with acne) in both situations.

Therefore, in the absence of evidence to the contrary or specific structural limitations, the prior art teachings clearly discloses the use of the claimed compounds to treat dermatological disease conditions of benign follicular hyperproliferation which includes acne and/or acneiform follicular reaction in a patient as well as to inhibit the proliferation of human sebaceous cells, and as such anticipates claims 6-8 and 11 as drafted.

CONCLUSION AND FUTURE CORRESPONDANCE

4. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272-0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abdel Mohamed/A. A. M./
Examiner, Art Unit 1654

/JON P WEBER/
Supervisory Patent Examiner, Art Unit 1657